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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,294	08/24/2001	Gregory J. Hinkle	16517.253	1056

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EXAMINER	
BUI, PHUONG T	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,294	HINKLE ET AL.	
	Examiner	Art Unit	
	Phuong T. Bui	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's Request for Continued Examination (RCE) filed February 1, 2006. Claims 19-23 are pending and are examined in the instant application. All previous rejections not set forth below have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, 2nd paragraph

2. Claims 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since "a complement" reads on a single nucleotide, which does not appear to be Applicant's intention, it is suggested that Applicant amend to recite "fully complementary". Clarification and/or correction are required.

Claim Rejections - 35 USC § 101 Utility

3. Claims 19-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility. The claims are directed to a nucleic acid molecule having 90-100% sequence identity with SEQ ID NO:2 which is "capable of reducing expressing levels in a plant or plant cell". The specification disclosed the claimed invention can be used "to develop nutritionally and agriculturally enhanced crops and products" and "aid gene expression studies that allow the dissection and elucidation of commercially useful traits" (p. 2, lines 1-6). The specification does not disclose what protein SEQ ID NO:2 encodes or any trait the claimed invention can be used to enhance, or how the claimed invention can be

used to enhance such trait. Under current utility guidelines, the claimed invention lacks specific and substantial asserted utility for the following reasons. First of all, if a plant gene affects plant growth or development in any way, positively or adversely, then the gene is directly or indirectly involved in "nutritionally and agriculturally enhanced crops and products". Thus this asserted utility is not specific to any particular class or group of plant genes, as most if not all plant genes would fulfill this asserted utility. The recitation of "capable of reducing expressing levels in a plant or plant cell" is also not specific because the expression level of any gene, known or unknown, can be reduced by prior art means such as by antisense or defective interfering RNAs. However, what is not known is why one skilled in the art would want to do this, or what useful result can be obtained by reducing expression levels of SEQ ID NO:2, or reducing expression levels of other gene(s) as a consequence of reducing the expression of SEQ ID NO:2. To simply reduce the expression levels is not sufficient to meet the specific utility requirement because this characteristic is not specific to any particular class of genes but would be common to ALL genes. Secondly, the claimed invention lacks substantial utility because a utility which requires or constitutes carrying out further research to identify or reasonably confirm a real world context of use is not a substantial utility. In *Brenner v. Manson*, the court established:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an Appellant to engross what may prove to be a broad field. (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while reducing expression levels of a gene to provide or enhance a commercially useful trait such as disease resistance would be a substantial benefit to the public, it is

unclear what benefit would be obtained by reducing the expression level of SEQ ID NO:2. Identifying, characterizing and sequencing a nucleic acid molecule are not substantially useful, absent some correlation with a recognized benefit. Would reducing the expression level of SEQ ID NO:2 result in a more disease-resistant plant, more disease-susceptible plant, more seeds, less seeds? All these traits have recognized benefits, even a disease-susceptible plant. However, it is unclear what trait is correlated with the claimed sequence, or how said sequence should be used to enhance said trait. Accordingly, the claimed invention lacks specific and substantial utility. Note, because the claimed invention is not supported by a specific, substantial asserted utility for the reasons set forth above, credibility cannot be assessed.

In addressing well-established utility, since the claimed invention lacks asserted utility for the reasons set forth above, the claimed invention also lacks well-established utility, such as probes and primers for use in hybridization assays. While one skilled in the art can readily generate probes and primers from the claimed sequence, it is unclear how probes and primers of a gene of undisclosed function would be useful to the public. Accordingly, the claimed invention also lacks well-established utility.

Thus, the claimed invention lacks utility under current utility guidelines (Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Applicant traverses primarily that 1) the claimed invention has specific and substantial utility consistent with *In re Fisher* because the claimed sequence can be used to reduce expression of an endogenous gene, transform plants, and reduce

expression of a desired protein; 2) the Office must do more than merely question operability; and 3) the Office has not assessed the credibility of the asserted utilities.

Applicant's traversals have been carefully considered but are found unpersuasive for the following reasons. A *Zea mays* sequence of unknown function and no identifiable correlation to any useful plant trait does not provide any immediate benefit to the public. The "uses" set forth by Applicant—reduce expression of an endogenous gene, transform plants, and reduce expression of a desired protein—are not uses but things one skilled in the art can do to ANY nucleic acid molecule. It is the identified real-world benefit obtained from doing these things that would be of value to the public. While one skilled in the art can readily transform a plant with SEQ ID NO:2, it is unclear what real-world use can be obtained by the transformation. Thus, the Office is not "merely question[ing its] operability"—whether or not one can transform a plant—but WHY would one want to, what useful result can be achieved by doing so. It is true that only a single utility is necessary to satisfy Section 101, but the utility must be credible, specific and substantial. Here none of Appellant's utilities meets the specific and substantial requirements. The characteristics as disclosed by Appellant are not limited to any particular gene or class of genes but would apply to all nucleic acid molecules. With regard to credibility, credibility cannot be assessed when the claimed invention lacks utility. When an invention has utility, then a determination as to whether or not the utility is credible can then be made.

Claim Rejections - 35 USC § 112, first paragraph

4. Claims 19-23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. With regard to claims having less than 100% sequence identity to SEQ ID NO:2 and "capable of reducing expression levels", the breadth of these claims encompasses unspecified base substitutions, deletions, additions, and combinations thereof while retaining the recited activity. Even though the function set forth in the claims cannot be assessed for the reasons set forth in the utility rejection above, it is unpredictable that whatever function inherent in SEQ ID NO:2 can be retained in sequences having less than 100% sequence identity to SEQ ID NO:2. Neither the state of the prior art nor Applicant teaches what bases of SEQ ID NO:2 must be retained for activity. One skilled in the art would not be able to predictably and reliably determine which sequences within the 90-99% sequence identity limitation would have the claimed activity other than by trial and error, or how inoperable embodiments can be readily eliminated without undue experimentation. While one skilled in the art can readily make mutations to these sequences, further guidance is needed as to what mutations would not ablate activity. Applicant provided no working example of any mutant sequences

within the 90-99% sequence identity scope which has the recited activity. Accordingly, the claimed invention cannot be practiced without undue experimentation as commensurate in scope with the claims.

6. Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims reciting 90-99% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass genes from other species which also are "capable of reducing expression levels in a plant or plant cell". The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:2 isolated from *Zea mays*. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and genes from other plants and organisms which have the same activity as SEQ ID NO:2, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

Remarks

7. No claim is allowed. SEQ ID NO:2 is free of the prior art.

8. Any inquiry concerning this communications from the Examiner should be directed to Phuong Bui, whose telephone number 571-272-0793.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975.

The fax phone number for the organization where this application or proceeding is assigned, for sending official correspondence, is 571-273-8300.

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Phuong T. Bui 3/20/06
Primary Examiner
Art Unit 1638

03/18/06